

- Sub
FI
C1
1. (Twice Amended) A tablet comprising crystals of a pharmaceutically acceptable salt of citalopram, wherein the median particle size of the crystals is at least 40 μm , which is prepared by direct compression of the pharmaceutically acceptable salt and pharmaceutically acceptable excipients.

2. (Twice Amended) The tablet according to claim 1 which does not contain a binder.

Sub
FI

3. (Twice Amended) The tablet according to claim 1 which contains 2-60% w/w active ingredient calculated as citalopram base.

C2

4. (Twice Amended) The tablet according to claim 1 which contains a filler selected from lactose, sugars, calcium phosphates, starch, modified starches, microcrystalline cellulose, calcium sulfate and calcium carbonate.

5. (Twice Amended) The tablet according to claim 4, wherein the filler is a microcrystalline cellulose.

6. (Twice Amended) The tablet according to claim 1 which contains a lubricant selected from metallic stearates, stearic acid, wax, hydrogenated vegetable oil, talc and colloidal silica.

Sub
F-1
cont.
C2
cont.
~~7-9.~~ (Twice Amended) The tablet according to claim ~~8~~⁶, wherein the lubricant is magnesium stearate or calcium stearate.

~~8-10.~~ (Twice Amended) The tablet according to claim 1 which is substantially free of lactose.

Sub
F-1
C3
~~9-12.~~ (Twice Amended) The tablet according to claim 1 wherein the pharmaceutically acceptable salt is citalopram hydrobromide or citalopram hydrochloride.

~~10-13.~~ (Twice Amended) The tablet according to claim ~~12~~⁹, wherein the pharmaceutically acceptable salt is citalopram hydrobromide.

C4
~~15-20.~~ (Twice Amended) Method for manufacture of crystals of a pharmaceutically acceptable salt of citalopram having a median particle size of at least 40 μ m, said method comprising the steps of forming a solution of a pharmaceutically acceptable salt of citalopram in a solvent system at a first temperature, cooling the solution to a second temperature, seeding the solution by addition of crystals of said citalopram salt, followed by holding the solution at said second temperature and a controlled cooling the solution down to a third temperature, and isolating said crystals.

C5
~~17-22.~~ (Twice Amended) The method according to claim ~~20~~¹⁵, wherein the pharmaceutically acceptable salt of citalopram is citalopram hydrobromide or citalopram hydrochloride.

C5
cat

18-23

(Twice Amended) The method according to claim 22, wherein the

pharmaceutically acceptable salt of citalopram is citalopram hydrobromide.

C6

25-30

(Twice Amended) The method according to claim 20 wherein the step of holding the solution at said second temperature is from 30 minutes to 7 days.

C7

28-33

(Twice Amended) The method according to claim 20 wherein the step of isolating the crystals of a pharmaceutically acceptable salt of citalopram is performed by filtration.

Sub
F1

29-36

(Amended) The tablet of claim 1, which contains 10-40% w/w active ingredient calculated as citalopram base.

C8

30-37

(Amended) The tablet of claim 1, which contains 15-25% w/w active ingredient calculated as citalopram base.

31-38

(Amended) The tablet of claim 6, wherein said filler is a sugar selected from the group consisting of sorbitol, mannitol, dextrose and sucrose.

32-39

(Amended) The tablet of claim 6, wherein said filler is a calcium phosphate selected from the group consisting of dibasic, tribasic, hydrous and anhydrous calcium phosphate.

33 ~~40.~~

(Amended) The tablet of claim ~~8~~⁶, wherein said lubricant is a metallic stearate selected from the group consisting of magnesium, calcium and sodium stearate.

34 ~~41.~~

(Amended) The tablet of claim 1, wherein the crystals have a median particle size of 40-200 μ m.

35 ~~42.~~

(Amended) The tablet of claim 1, wherein the crystals have a median particle size of 45-150 μ m.

36 ~~43.~~

(Amended) The tablet of claim 1, wherein the crystals have a median particle size of 50-100 μ m.

48 ~~55.~~

(Amended) The method according to claim ~~30~~²⁵, wherein the step of holding the solution at said second temperature is from 1 hour to 4 days.

49 ~~56.~~

(Amended) The method according to claim ~~30~~²⁵, wherein the step of holding the solution at said second temperature is from 12 to 36 hours.